

### **REMARKS**

Attorney for applicants has carefully reviewed the outstanding Office Action on the above-referenced application. Applicants have amended Claims 26-29 and added new Claims 39-44.

The August 10th Office Action has been made final. In such circumstances, a Request for Continued Examination ("RCE") is enclosed herewith to expedite prosecution of the present application.

The Examiner has not entered the amendment to the specification presented in the Amendment mailed April 27, 2007 because she contends that the amendment was adding more than what was originally disclosed. Applicants note that support for this amendment can be found in the original drawings. For example, Figure 1 discloses a discrete layer of the porous ceramic phase 14 positioned on top of the interphase region 16. However, applicants have modified the paragraph that was previously presented. Because the previous amendment to the specification was not entered, applicants have amended the specification to add a new paragraph. Support for this amendment can be found in at least the originally filed drawings. Hence, the amendment to the specification does not constitute new matter.

The Examiner has rejected Claims 26-28 and 33 under 35 U.S.C. 103(a) as being unpatentable over the Niederauer et al. reference. Claims 26-33 have been rejected under 35 U.S.C. 103(a) as being unpatentable over the Niederauer et al.



reference in view of Vyakarnam et al. U.S. Patent No. 6,306,424. These claim rejections are respectfully traversed for the following reasons.

Independent Claim 26 relates to a “method for repairing a defect area at the gradient junction of cartilaginous tissue and bony tissue,” which includes “providing a composite scaffold with a porous ceramic phase including a discrete ceramic layer, a porous polymer phase including a discrete polymer layer, the polymer phase attached to the ceramic phase at an interphase region where the polymer phase is at least partially infused into the ceramic phase mechanically interlocking the ceramic and polymer phases, with the porosity of the ceramic and polymer phases communicating.” The “interphase region [is] situated between the discrete ceramic layer of the porous ceramic phase and the discrete polymer layer of the porous polymer phase.” See, e.g., Claim 26 (emphasis added). Claim 26 further includes “boring a receptacle space in the gradient junction at the site of the injury to receive the scaffold, the gradient junction being that of articular cartilage,” and “placing and securing the scaffold in the receptacle space with the ceramic phase adjacent to the bony tissue and the polymer phase adjacent to the cartilaginous tissue.” See Claim 26 (emphasis added). Thus, the scaffold recited in Claim 26 clearly has at least two phases and a mechanism (i.e., the interphase region) for providing attachment of the phases to each other.

It is respectfully submitted that the Niederauer et al. reference does not anticipate or make obvious the present invention as recited in Claim 26. The scaffold disclosed in the Niederauer et al. reference is prepared from layers of polylactic/polyglycolic acid (PLG) and either Bioglass particles or calcium sulfate. The



scaffold disclosed in the Niederauer et al. reference is significantly different from the novel scaffold recited in Claim 26. The scaffold disclosed in the Niederauer et al. reference may include a ceramic and a polymer. However, the ceramic and the polymer are simply blended with each other (see the Niederauer et al. reference, third and fourth paragraphs on the left column of page 2563) and the phases glued together (see the Niederauer et al. reference, sixth paragraph on the left column of page 2563). There is no disclosure or suggestion in the Niederauer et al. reference of an **"interphase region** where the polymer phase is at least partially **infused** into the ceramic phase mechanically **interlocking** the ceramic and polymer phases, with the porosity of the ceramic and polymer phases communicating," as recited in Claim 26. See Claim 26 (emphasis added).

Further, the blended polymer phase and the ceramic phase disclosed in the Niederauer et al. reference are not arranged in any particular manner. In contrast, the scaffold of the present invention includes a "discrete ceramic layer," a "discrete polymer layer," and an interphase region "situated between the discrete ceramic layer of the porous ceramic phase and the discrete polymer layer of the porous polymer phase," as recited in Claim 26. See Claim 26 (emphasis added).

The ceramic phase of the present invention is placed "adjacent to the bony tissue," while the polymer phase is placed "adjacent to the cartilaginous tissue." See Claim 26. The Examiner concedes that the Niederauer et al. reference does not disclose the step of placing and securing the scaffold in the receptacle space with the ceramic phase adjacent to the bony tissue and the polymer phase adjacent to the



cartilaginous tissue. As previously discussed, the ceramic and the polymer of Niederauer et al. are simply blended with each other and glued together. The Niederauer et al. reference does not disclose or suggest a ceramic phase, a polymer phase discrete and separate from the ceramic phase after fabrication, and an interphase region. Hence, it would not be obvious to one skilled in the art to modify the blended ceramic and polymer phases of Niederauer et al. to form discrete phases.

In view of the distinctions discussed above, it is respectfully submitted that the Niederauer et al. reference fails to disclose or suggest the method recited in Claim 26.

With respect to the Vyakarnam reference, it does not disclose or suggest any interaction between a polymer phase and a ceramic phase, much less an "interphase region where the polymer phase is at least partially **infused** into the ceramic phase mechanically **interlocking** the ceramic and polymer phases, with the porosity of the ceramic and polymer phases communicating," as recited in Claim 26 (emphasis added). Therefore, applicants' attorney respectfully submits that the Vyakarnam reference, whether considered individually or in combination with the Niederauer et al. reference, does not anticipate or make obvious the present invention as recited in Claim 26.

In the foregoing circumstances, Claim 26 is believed to be in condition for allowance. Because Claims 29, 30, 33, and 34 and new Claims 39 and 42 depend, either directly or indirectly, from Claim 26, they are also believed to be in condition for allowance. Nevertheless, applicants' attorney notes that the dependent claims recite



additional novel features of the present invention. For instance, Claim 34 requires that “the discrete polymer layer of the porous polymer phase is positioned on only one side of the interphase region.” None of the references disclose or suggest a “discrete polymer layer of the porous polymer phase...positioned on only one side of the interphase region.”

Independent method Claims 27 and 28 are very similar in scope to that of independent method Claim 26. More particularly, both Claims 27 and 28 include “providing a composite scaffold with a porous ceramic phase including a discrete ceramic layer, a porous polymer phase including a discrete polymer layer, the polymer phase attached to the ceramic phase at an interphase region where the polymer phase is at least partially infused into the ceramic phase mechanically interlocking the ceramic and polymer phases, with the porosity of the ceramic and polymer phases communicating.” See Claims 27 and 28 (emphasis added). As further recited in Claims 27 and 28, the interphase region is “situated between the discrete ceramic layer of the porous ceramic phase and the discrete polymer layer of the porous polymer phase.” See Claims 27 and 28 (emphasis added). In such circumstances, Claims 27 and 28 are patentably distinguishable over the Niederauer et al. and the Vyakarnam references for the reasons discussed above. Accordingly, independent Claims 27 and 28 are believed to be in condition for allowance.

Claims 31, 35, 36, 40, and 43 depend, either directly or indirectly, from Claim 27, while Claims 32, 37, 38, 41, and 44 depend, either directly or indirectly, from Claim 28. Accordingly, Claims 31, 32, 35-38, 40, 41, 43, and 44 are also believed to be



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in condition for allowance.

In view of the foregoing amendments and remarks, applicants' attorney respectfully requests reexamination and allowance of pending Claims 26-38, and examination and allowance of new Claims 39-44. If such action cannot be taken, the Examiner is cordially invited to place a telephone call to applicants' attorney in order that any outstanding issue may be resolved without the issuance of a further Office Action.

Enclosed is a Request for Continued Examination Transmittal Form which authorizes payment of the RCE filing fee. If there are any additional fees due as a result of this Amendment, including extension and petition fees, the Examiner is authorized to charge them to Deposit Account No. 503571.

Respectfully Submitted,

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